K121530

# Traditional 510(k)
# 510(k) Summary

JUN 20 2012

## BodyFIX System

**BodyFIX - 510(k) Summary**

| | | |
|---|---|---|
| 1. | Applicant | Medical Intelligence Medizintechnik GmbH |
| 2. | Address | Robert-Bosch-Straße 8<br>Schwabmuenchen<br>86830<br>Germany |
| 3. | Contact Person | Michael Wolff, +49 (0) 8232 9692 701 |
| 4. | Preparation Date | April 19th, 2012 / June 13th, 2012 |
| 5. | Device Submitted | BodyFIX System |
| 6. | Proprietary Name | BodyFIX |
| 7. | Common Name | BodyFIX |
| 8. | Classification Name | Accelerator, Linear, Medical |
| 9. | Substantial Equivalence | The BodyFIX System is substantially equivalent in terms of intended use to the following currently marketed device: BodyFIX (K013391). |
| 10. | Device Description | The BodyFIX System is a patient positioning and immobilization device for use with radiotherapy, radiosurgery, sonography, surgery/CAS, imaging neurosurgery and brachytherapy treatments of extracranial targets. The principal parts of the system include the vacuum cushion, cover sheet, vacuum supply (vacuum pump), target positioner and localizer, and carbon fiber baseplate.<br>The BodyFIX Vacuum Pump P3 is a high-performance vacuum pump that contains two separate pumps; the BlueBAG pump and the BodyFIX pump.<br><br>1- BlueBAG - pump provides the vacuum for inflating, forming and deflating the BlueBAG vacuum cushions. |

# Traditional 510(k)
# 510(k) Summary

## BodyFIX System

| | | |
|---|---|---|
| Dimensions | 600 x 988 x 510 (approx) | 580 x 410 x 355 (approx) |
| Construction Material | Carbon fibre sandwich with hard foam core | |
| Stereotactic fiducial built into frame | Yes | |
| Weight | 77 kg (approx) | 39 kg (approx) |
| Noise | 60dB (A) | |
| Operation Mode | Continuous (unattended running) | |
| Power | 1000 VA (max) | 1100 VA |
| Voltage | 100; 110; 120; 230; 240; V AC | |
| Current | 8 A (max) | |
| Fuses | T8 A/250 V AC | |
| Metohod of suppressing diaphragmatic movement | Plastic fixation sheet and stabilising cushion | Plastic fixation sheet and stabilising cushion |
| Fixation | Vacuum cushion and plastic fixation sheet | Vacuum cushion and plastic fixation sheet |
| Imaging studies | CT and/or MRI for treatment planning | |
| Clinical Applications | Patient positioning and immobilisation, thoracic, abdominal, pelvic, arm and leg therapeutic targets | |
| Transversal plane CT localisation error x,y | Mean 0.5 ±0.7 mm | |
| Longitudinal plane localisation error z | Range 0.3 – 2.0 mm | |
| Linac set-up error | 1.0 mm approx | |
| Anterior Body Form (immobilisation) | Yes | Yes |
| Posterior Body Form (immobilisation) | Yes | Yes |
| Treatment Modality | Photon linear accelerator | Photon linear accelerator |
| Immobilisation | Non-invasive | Non-invasive |
| HF Emissions (CISPR 11) | Class B | Class B |
| Electromagnetic Environment Guidelines | The unit or system solely uses HF-energy for its internal function. Therefore its HF emissions are very low, and | The unit or system solely uses HF-energy for its internal function. Therefore its HF emissions are very low, and |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael Wolff
Regulatory Affairs Manager
Medical Intelligence Medizintechnik GMBH
Robert-Bosch-Strabe 8
SCHWABMUNCHEN 86830
GERMANY

JUN 20 2012

Re: K121530
Trade/Device Name: BodyFIX® System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 4, 2012
Received: May 24, 2012

Dear Mr. Wolff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): _____

Device Name: BodyFIX® System

Indications for Use:

This product is intended to be used by radiologists and surgeons for the following:

- Patient positioning and immobilization
- Stereotactic diagnostic localization
- Patient positioning and immobilization device for stereotactic radiotherapy of extracranial targets

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K k121530